Remarks

Reconsideration and withdrawal of the rejections of the claims, in view of the remarks presented herein, is respectfully requested. Claims 1 and 8 are amended, and claims 2, 4-5, 9, 11 and 14-22 are canceled without prejudice or disclaimer. Thus, the pending claims are claims 1, 3, 6-8, 10 and 12-13.

The amendments to the claims are fully supported by the specification as filed. No new matter has been added by way of these amendments.

The Examiner rejected claims 1-3, 6-8, 10 and 12-13 under 35 U.S.C. §103(a) as being unpatentable over Ginsburg (U.S. Patent No. 5,180,364). The cancellation of claim 2 renders this rejection to claim 2 moot. As this rejection may be maintained with respect to the pending claims, it is respectfully traversed.

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation either in the cited references themselves, or in the knowledge generally available to an art worker, to modify the reference or to combine reference teachings so as to arrive at the claimed invention. Second, the art must provide a reasonable expectation of success. Finally, the prior art reference must teach or suggest all the claim limitations. M.P.E.P. § 2143. The teaching or suggestion to arrive at the claimed invention and the reasonable expectation of success must be found in the prior art, not in Applicant's disclosure. M.P.E.P. § 2143 citing with favor *In re* Vaeck, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991).

As amended, the claims are directed to a venous cannula, comprising a body having a proximal end sized and adapted for connection to a cardiac bypass system and a distal end, the body having a wall defining a lumen extending from the proximal end to the distal end, the lumen having a longitudinal axis; the body being sized and shaped to afford placement of the cannula in a portion of the venous system of a patient, and a plurality of valveless apertures in the wall interconnected with the lumen and permitting fluid flow from outside the lumen into the lumen for transport through the lumen, wherein the apertures have first and second corners defined by arcuate portions that

intersect with each other, wherein each of the apertures has a longer major axis and a shorter minor axis with the first and second corners along the longer major axis, and wherein the longer major axis is perpendicular to the longitudinal axis of the lumen; and to a venous cannula, comprising a body having a proximal end sized and adapted for connection to a cardiac bypass system and a distal end, the body having a wall defining a lumen extending from the proximal end to the distal end, the lumen having a longitudinal axis; the body being sized and shaped to afford placement of the cannula in a portion of the venous system of a patient, and a plurality of valveless apertures in the wall interconnected with the lumen and permitting fluid flow from outside the lumen into the lumen for transport through the lumen, wherein the apertures include first and second corners defined by arcuate portions that intersect with each other such that the corners do not buckle outwardly as the cannula is flexed.

Ginsburg discloses a guiding catheter including an elongate body having a lumen and on the distal end of the body "a plurality of valved passageways" that provide "selective communication" between the lumen and the region outside the body (column 2, lines 59-64; column 4, lines 18-25). Ginsburg discloses that the valved passageways can be any type of opening, of any shape, size, or position along the distal end of the catheter body, and may also be random in their configuration and location (column 5, lines 21-23 and 29-33). Ginsburg discloses that each valved passageway "acts as a one-way valve" to restrict fluid flow through the catheter to one direction (column 2, lines 65-66; column 4, lines 26-27). For example, Ginsburg discloses that when a contrast agent is injected into the catheter during an imaging procedure, such as angiography, it is not "lost to the surrounding vasculature" but is rather delivered by the distal end of the catheter (column 2, line 65-column 3, line 4; see also FIGs 4-7).

However, Ginsburg do not disclose or suggest to a venous cannula, let alone one comprising a body having valveless apertures. Moreover, there is nothing in Ginsburg that discloses or suggests a venous cannula having valveless apertures having first and second corners defined by arcuate portions that intersect with each other, wherein each of

the apertures has a longer major axis and a shorter minor axis with the first and second corners along the longer major axis, and wherein the longer major axis is perpendicular to the longitudinal axis of the lumen. Furthermore, Ginsburg does not disclose or suggest such a venous cannula having aperture corners that do not buckle outwardly as the cannula is flexed. Thus, Ginsburg does not render the pending claims obvious.

Applicants' respectfully submit that *prima facie* obviousness has not been established. As discussed above, Ginsburg does not teach or suggest all the limitations of the pending claims. Applicants' respectfully disagree with the Examiner's assertions that Ginsburg discloses (i) an aperture which is eye-shaped; and (ii) an aperture having two corners having a major axis which is perpendicular to the longitudinal axis of the catheter or cannula" (page 3 of the final Office Action). Paragraph [0027] of the application as filed discloses that an "eye-shaped aperature" is an

> "aperature defined by first arcuate portion . . . and second arcuate portion . . . that intersect with one another at two tips or corners . . . [and]. . . a longer major axis . . . and a shorter minor axis . . .

Applicants' are unable to locate the disclosure or suggestion of (i), above, in Ginsburg, let alone the disclosure or suggestion of an aperature having first and second arcuate portions that intersect with one another at two tips or corners and a longer major axis and a shorter minor axis. In addition, Applicants' are unable to locate the disclosure of (ii), above, in Ginsburg. Moreover, Applicants' note that the Examiner has conceded that Ginsburg "does not explicitly show [an aperature having] a major and minor axis, which is perpendicular to the longitudinal axis of the cannula . . ." (page 2 of the final Office Action). Thus, it is clear that the cited art does not teach or suggest all the limitations of the pending claims.

There is nothing in Ginsburg that would provide an art worker with the necessary motivation to modify the reference so as to arrive at the presently claimed venous cannula. First, Ginsburg is directed to solving a completely different problem in the art, *viz.*, Ginsburg is directed to restricting the flow of fluid from a catheter (for precise delivery of a contrast agent), whereas the present application is directed to maintaining

the flow of fluid from a cannula (by preventing kinking of the cannula and buckling of the aperatures). In addition, given Ginsburg's disclosure that "self-perfusing guides . . . are poorly adapted for angiography techniques because large amounts of contrast media are typically lost to the surrounding vasculature," which loss "interfere[s] with angiography" and increases the risk of contrast toxicity, Applicants' submit that the art worker would not be motivated to replace the one-way valved passageways of the Ginsburg catheter with a valveless apertures of the present invention, and would not have a reasonable expectation that such catheter would be successful.

Moreover, given the disclosure by Ginsburg that the passageways can be "any" shape, Applicants' submit that Ginsburg actually *teaches away* from apertures having a particular shape, let alone apertures having "first and second corners defined by arcuate portions that intersect with each other, wherein each of the apertures has a longer major axis and a shorter minor axis with the first and second corners along the longer major axis, and wherein the longer major axis is perpendicular to the longitudinal axis of the lumen" or the "eye-shaped" aperatures as claimed in the present invention. In addition, Applicants' submit that the disclosure by Ginsburg that the passageways can be randomly distributed on the catheter *teaches away* from aperatures having a particular pattern of distribution, let alone apertures that are "arranged into a plurality of rows generally extending along the longitudinal axis of the lumen" and apertures that are "evenly distributed on the body . . . offset such that the apertures in the adjacent rows are different distances from a distal tip of the body" as claimed in the present invention.

Therefore, for the reasons discussed above, it is respectfully submitted that the pending claims are not *prima facie* obvious over Ginsburg. Withdrawal of the 35 U.S.C. §103(a) rejection of the claims is thus proper and respectfully requested.

Conclusion

Applicants respectfully submit that the claims are in condition for allowance, and notification to that effect is respectfully requested. The Examiner is invited to telephone Applicants' Representative at 763-391-9634 to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 13-2546.

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By

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